PMH42

COST-UTILITY ANALYSIS OF LISDEXAMFETAMINE IN THE TREATMENT OF CHILDREN AND ADOLESCENTS WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER IN THE UNITED KINGDOM

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OBJECTIVES: An economic analysis was conducted from the United Kingdom's (UK's) National Health Service (NHS) perspective to evaluate the cost-effectiveness of lisdexamfetamine (LDX) versus atomoxetine (ATX) in treating children and adolescents with attention-deficit/hyperactivity disorder (ADHD) who have had an inadequate response to methylphenidate (MPH). **METHODS:** A 1-year probabilistic decision-analytic model with a Markov structure of nested decision trees was constructed. Health states included "response", "non-response", and "unable to tolerate". Key model assumptions were adapted from a technology assessment for ADHD products by the National Institute for Health and Care Excellence. The analysis used clinical data from a head-to-head randomized controlled trial in inadequate responders to MPH. Response to treatment was defined as a score of 1 (much improved) or 2 (improved) on the Clinical Global Impression-Improvement scale. Tolerability was assessed by rates of discontinuation due to adverse events. Utility weights were identified via a systematic literature review. Health care resource use estimates for responders and non-responders were obtained via a survey of UK specialists. Unit costs from national sources were applied to estimate the corresponding health-state costs. Daily drug costs were based on mean doses reported in the trial. One-way and probabilistic sensitivity analyses were performed. **RESULTS:** The comparison of LDX and ATX, using head-to-head data, resulted in an incremental cost-effectiveness ratio (ICER) of £1,802 per quality-adjusted life year (QALY). At a willingness to pay of £20,000 per QALY, LDX had an 86% probability of being cost-effective compared with ATX. In 38% of sensitivity analysis runs, LDX was a dominant strategy over ATX. The model was slightly sensitive to changes in assumptions about drug costing and to lengthening the titration period for ATX. **CONCLUSIONS:** From the perspective of the UK NHS, LDX provides a cost-effective treatment option for children and adolescents with ADHD who are inadequate responders to MPH.

PMH43

COST-EFFECTIVENESS OF ASENAPINE IN THE TREATMENT OF BIPOLAR DISORDER I PATIENTS WITH MIXED EPISODES

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OBJECTIVES: The cost-effectiveness of second-generation antipsychotic drugs is well established in the treatment of patients experiencing a manic episode associated with bipolar I disorder. However, no studies demonstrating the value of these drugs in patients with mixed episodes according to DSM-IV have so far been undertaken. The aim of this study was to assess the cost-effectiveness of asenapine versus olanzapine in the treatment of this costly subgroup of patients. **METHODS:** A 9-week acute phase model was developed, during which patients receive up to three lines of treatment: asenapine or olanzapine alone, then adjunctive valproate, and finally a switch to adjunctive lithium. Patients can respond during any 3-week period and non-responders move to the next treatment in the sequence. Efficacy of asenapine (46.3%) and olanzapine (37.5%) was informed by a post-hoc analysis of two short-term clinical trials, where response was measured as a composite YMRS and MADRS endpoint. Following initial treatment, patients entered a 5-year maintenance Markov model during which they faced probabilities of treatment discontinuation, recurrent manic, mixed and depressive symptoms and death. Direct costs (year 2012-13 values), including drug, monitoring costs and resource use related to bipolar disorder and selected adverse events, were assessed from a UK NHS perspective. Benefits were measured as quality-adjusted life years (QALYs). **RESULTS:** For patients with a mixed episode, asenapine was a more effective and less costly treatment strategy compared with olanzapine over a 5-year period. Greater health benefits and cost savings were driven by earlier response to asenapine treatment during the acute phase and were well maintained during longer-term follow-up. These results were robust to changes in key parameters including short and longer-term efficacy, unit cost and utility values. **CONCLUSIONS:** Compared with olanzapine, results of this analysis suggest that asenapine generates greater health benefits at lower cost in the treatment of patients experiencing mixed episodes associated with bipolar I disorder.

PMH44

C-QUALITY: A COST AND QUALITY OF LIFE PHARMACOECONOMIC ANALYSIS OF ANTIDEPRESSANTS IN MAJOR DEPRESSIVE DISORDER IN ITALY

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OBJECTIVES: To assess the cost-effectiveness (€ per quality-adjusted life year [QALY]) of all Selective serotonin reuptake inhibitors (SSRIs) and all Serotonin-norepinephrine reuptake inhibitors (SNRIs) for the treatment of Major Depressive Disorder (MDD) in Italy. **METHODS:** A decision analytic model was adapted from the Swedish Dental and Pharmaceutical Benefits agency model to reflect current clinical practice in the treatment of MDD in the largest Italian regions. This adaptation was possible thanks to the collaboration of an expert panel of Italian psychiatrists and health economists. The model evaluated patients with a first diagnosis of MDD and initiating an SSRI or an SNRI for the first time. The time horizon was 12 months. Efficacy and utility data for the model were retrieved from the literature and validated by the expert panel. Local data were considered for resource utilization and for treatment costs based on each regional health service perspective. Population-weighted regional data were used to define a national model. Scenario simulations, one-way sensitivity analyses, and Monte Carlo simulations were performed to test the robustness of the model. **RESULTS:** The base case analysis showed that escitalopram was associated with a lower total cost (€1,562) and a larger health gain (QALYs) at one year (0.732) per patient, and dominated the other treatment strategies since more QALYs were achieved at a lower total cost. Sensitivity analyses support the robustness of the model. **CONCLUSIONS:** The results indicate that escitalopram is the most cost-effective pharmacological treatment strategy for the Italian health service compared with other SSRIs and all SNRIs used in the first-line treatment of MDD.

PMH45

COST EFFECTIVENESS OF PALIPERIDONE PALMITATE IN NATIONAL HEALTH SERVICE (NHS) WALES: A COST UTILITY ANALYSIS BASED ON THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) CORE MODEL FOR THE MANAGEMENT OF SCHIZOPHRENIA

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OBJECTIVES: Paliperidone palmitate has demonstrated non-inferior efficacy to risperidone long acting injectable (LAI) for the treatment of schizophrenia in previous studies. The objective of this analysis was to assess the cost effectiveness of paliperidone palmitate relative to risperidone LAI, based on the cost-utility analysis described in the current NICE Guidelines for the Management of Schizophrenia. The analysis was undertaken from the perspective of NHS Wales and was submitted to the All Wales Medicines Strategy Group for evaluation. **METHODS:** A decision-analytic Markov model was developed to estimate the cost-utility of paliperidone palmitate relative to risperidone LAI. The model adopted an annual cycle length. Patients who entered the model initiated either paliperidone palmitate or risperidone LAI and could subsequently transition between five health states during each annual cycle. AEs associated with each intervention were derived from literature. Utility values were derived from a community-based study, using trade-off technique to elicit HRQoL for schizophrenia according to frequency of injections. Resource use data was sourced from the NICE core model/guidelines, Welsh clinical experts, and a UK Delphi panel. Unit costs were derived from the British National Formulary, NHS reference costs, and the Personal Social Services Research Unit reports. Costs and outcomes were evaluated over a 10-year horizon, and discounted at 3.5%. Results were presented as incremental costs/QALY. Uncertainty was addressed via deterministic and probabilistic sensitivity analyses. **RESULTS:** The base case analyses demonstrated that paliperidone palmitate would incur lower costs (-£3,773) and generate more quality adjusted life years (QALYs) (+0.13) than risperidone LAI. This indicated that paliperidone palmitate 'dominated' risperidone LAI. Extensive scenario/sensitivity analyses confirmed the robustness of the results **CONCLUSIONS:** Compared with risperidone LAI, paliperidone palmitate is a cost-effective therapy for the treatment of schizophrenia in adult patients in NHS Wales.

PMH46

COST-UTILITY ANALYSES OF COGNITIVE-BEHAVIORAL THERAPY FOR MAJOR DEPRESSIVE DISORDER – A SYSTEMATIC REVIEW

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OBJECTIVES: Major depressive disorder (MDD) causes a massive health and economic burden for societies worldwide. Cognitive behavioural therapy (CBT) is an inherent part of the treatment of MDD and is recommended for children, adolescents and adults. Cost-Utility-Analysis (CUA) is an important instrument to support decision-making on resource allocation and health policy as it permits the comparison of interventions for different diseases. The objective of our study was to systematically review CUAs related to CBT in the treatment of patients suffering from MDD. **METHODS:** We conducted a systematic literature search in MEDLINE, EMBASE, PsycINFO and NHSEED. We included all original studies reporting CUA of CBT for patients suffering from MDD. Cost data were inflated to the year 2011 and converted into US-$ using purchasing power parities (US-$ PPP) to ensure comparability of the data. Quality assessment of the studies was performed by means of a standardised quality checklist. **RESULTS:** We identified 22 CUAs. The methodological quality was fair. Two studies considered a lifetime horizon. The mean time horizon of the remaining studies was 19.2 months (SD = 12.6). In most instances individual and group CBT as well as CBT for maintenance showed acceptable cost-utility ratios (ICER < 50.000 US-$-PPP / QALY). The results of CUAs of CBT provided for children and adolescents or by computer were inconsistent. In comparison to medication CBT tends to be more cost effective as stand-alone therapy and in combination with medication. **CONCLUSIONS:** Individual and group CBT is a cost effective treatment for MDD. Further research to determine the cost effectiveness of computerized CBT and of CBT for specific populations like children, adolescents or the elderly is required. Furthermore there is a need for long term evidence of cost effectiveness of CBT.

PMH47

COMPARISON OF HEALTH CARE RESOURCE UTILIZATION AND COSTS AMONG CHILDREN AND ADOLESCENTS WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER IN GERMANY WHO INITIATED TREATMENT WITH ATOMOXETINE OR LONG-ACTING METHYLPHENIDATE

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OBJECTIVES: This study compared health care resource utilization (HRU) and costs among children/adolescents with attention deficit/hyperactivity disorder (ADHD) in Germany who initiated treatment with atomoxetine (ATX) or long-acting methylphenidate (LA-MPH). **METHODS:** A retrospective propensity score matched cohort analysis was conducted using the IMS electronic medical record database comprising >15 million patient records from ~3,000 German physicians. Included patients were aged 6-17 years, with a first (index) ATX or LA-MPH prescription in 2006-2010; ≥1 ADHD diagnoses 12-month before (pre-index) and after (post-index) index; and ≥1 index medication prescription post-index. Patients in the ATX and LA-MPH

cohorts were matched 1:1 using "nearest neighbor" greedy match propensity score method. HRU (inpatient, outpatient, and medications) and costs were compared between the two cohorts. Unit costs were identified from German Diagnosis-related Group for inpatient, Einheitlicher Bewertungsmassstab doctor fee scale for outpatient, and Rote Liste® for medication costs. Direct medical costs over the post-index period were reported in 2011 Euros. Chi-square for categorical variables and t-test or Wilcoxon-Mann-Whitney for continuous variables were used to test for differences between cohorts (alpha=0.05). Generalized linear models with negative binomial (for HRU) and gamma (for cost) distributions were used to address residual differences between matched cohorts. **RESULTS:** Of 4705 eligible patients, 737 with ATX (mean age=10.9 years, 20.8% female) were identified and matched 1:1 with LA-MPH patients (mean age=11.2 years, 18.6% female). Patients initiating ATX had higher HRU and spending per-patient than patients initiating LA-MPH over the post-index: 20.9 (SD=11.5) vs. 15.7 (SD=9.0) outpatient prescriptions, 10.1 (SD=6.3) vs. 8.3 (SD=5.3) outpatient visits, €1029 (SD=574) vs. €496 (SD=334) in retail pharmacy costs, and €1,258 (SD=739) vs. €684 (SD=515) in total all-cause costs (all $p=<.0001$). **CONCLUSIONS:** Among children/adolescents with ADHD in Germany, ATX initiators consumed significantly more health care resources and were associated with significantly higher direct medical costs compared with LA-MPH initiators.

MENTAL HEALTH – Patient-Reported Outcomes & Patient Preference Studies

PMH48

FACTORS ASSOCIATED WITH POOR ADHERENCE IN PATIENTS INITIATING MEDICATION FOR MAJOR DEPRESSIVE DISORDER: INTERIM RESULTS FROM A PROSPECTIVE, LONGITUDINAL STUDY

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OBJECTIVES: To examine factors associated with low adherence in Major Depressive Disorder (MDD) patients initiating antidepressant medication (ADM) over a 12-week period. **METHODS:** MDD patients initiating an ADM (with no ADM claim in the 6 months prior) were identified from a large pharmacy benefits manager database. Patients completed paper or online assessments including demographics at baseline and patient-reported assessments at baseline, Week 4 and Week 12. Participants were classified as having low, medium, or high adherence based on the modified Morisky Adherence Scale, with the medium and high adherence groups combined for analysis. Logistic regression analyses were run to evaluate the association between adherence and age, gender, and patient-reported assessments of depression and sexual dysfunction (SD), weight gain, sleep problems, nausea, and anxiety. **RESULTS:** Of 2412 patients screened, 591 enrolled and completed baseline assessments. Mean age was 40.4 years (standard deviation=12.1), 82.4% were women, and 87.6% were white. There were 483 who completed Week 4 and 425 who completed Week 12 assessments. At Week 12, 39.6% were high adherers, 20.6% were medium adherers, and 39.8% were low adherers. Thirty-eight percent of low adherers had actually discontinued ADM. Among discontinuers, 40.6% discontinued due to ADM side effects. In logistic regression models, low adherence at Week 4 was significantly associated with weight change ≥5 pounds (OR=2.10, 95% CI: 1.32–3.35), anxiety (OR=1.73, 95% CI: 1.06-2.8) and nausea (OR=2.31, 95% CI: 1.06–5.02). Age, gender, depression severity, sexual dysfunction, and insomnia were not significant in the logistic model. No factors were significantly associated with adherence at Week 12. **CONCLUSIONS:** In this real-world study of patients with MDD, nearly 40% of patients were low adherers. Weight change, anxiety, and nausea were associated with low adherence at Week 4, but not at Week 12.

PMH49

ADHERENCE, SWITCHING, AND DISCONTINUATION DURING THE 12 WEEKS FOLLOWING ANTIDEPRESSANT INITIATION IN PATIENTS WITH DEPRESSIVE DISORDER: RESULTS OF A PROSPECTIVE, LONGITUDINAL STUDY

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OBJECTIVES: This study examined patterns of adherence, switching, and discontinuation, in major depressive disorder (MDD) patients initiating antidepressant medication (ADM) therapy. **METHODS:** Depressed patients recently initiating an ADM were identified from a large pharmacy benefits manager database. Eligible patients were invited to participate by phone or mail and enrolled patients completed. **RESULTS:** Of 2,412 patients screened, 591 were enrolled. Average age was 40.4 years (standard deviation=12.1), 82.4% of participants were women, and 87.6% were white. At Week 4 (n=483), 39.4% were classified as low adherers with 31 (6.4%) patients having discontinued ADM for reasons including side effects (n=14, 45.2%), feeling better (n=5, 16.1%), cost (n=5, 16.1%), and lack of efficacy (n=4, 12.9%). There were 27 (5.6%) patients who switched by Week 4. Of these, 12 (44.4%) switched due to side effects, 11 (40.7%) due to lack of efficacy, and 3 (11%) due to cost. By week 12 (n=425), 33 additional patients had discontinued ADM citing similar reasons as those at Week 4. Of 43 patients who reported switching at Week 4 or Week 12, 15 (34.9%) cited side effects, 16 (37.2%) cited lack of efficacy, and 4 (9.3%) cited cost. **CONCLUSIONS:** In this real-world, 12-week study of MDD patients initiating ADM, adherence to ADM was low. Switching and discontinuing ADM were common within the 12-weeks period and were primarily attributed to side effects and lack of efficacy.

PMH50

FUNCTIONAL OUTCOMES WITH ARIPIPRAZOLE ONCE-MONTHLY IN TWO DOUBLE-BLIND, PLACEBO- AND ACTIVE-CONTROLLED STUDIES (ASPIRE US 246 AND ASPIRE EU 247) FOR THE TREATMENT OF SCHIZOPHRENIA

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OBJECTIVES: To evaluate functional outcomes of aripiprazole once-monthly (ARI-OM) 400 mg (ARI-OM-400) versus a sub-therapeutic dose of ARI-OM (50 mg; ARI-OM-50), oral aripiprazole (ARI), and placebo, in two trials of stable patients with schizophrenia. **METHODS:** Detailed study designs have been reported previously. Results are reported for the double-blind, randomized phase of each study. ARI-OM is an extended-release injectable suspension given at 400 mg in the gluteal muscle. Functional outcome was measured using the Personal and Social Performance scale (PSP) and statistically analyzed using analysis of covariance with last observation carried forward. **RESULTS:** A total of 403 patients were randomized to ARI-OM-400 (n=269) or placebo (n=134) in the first (246) trial. PSP scores at endpoint significantly worsened with placebo (-6.2) versus ARI-OM-400 (-1.7; p=0.0002). In the second study (247), 662 patients were randomized to: ARI-OM-400 (n=265); ARI (n=266); or ARI-OM-50 (n=131). PSP scores with sub-therapeutic ARI-OM-50 significantly worsened (-2.39) versus ARI-OM-400 (+0.45; p=0.03). Similar functional stability was observed with ARI (+0.08). **CONCLUSIONS:** Patient functioning, as assessed by PSP, was maintained with ARI-OM in both studies but deteriorated in patients randomized to either sub-therapeutic doses or placebo, confirming the benefits of adequately dosed antipsychotic therapy in preserving functional stability in long-term management of schizophrenia.

PMH51

THE DEVELOPMENT AND VALIDATION OF A QUALITY OF LIFE MEASURE FOR PEOPLE WITH MILD COGNITIVE IMPAIRMENT (THE MCQ)

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OBJECTIVES: Mild cognitive impairment (MCI) is a state that lies between normal cognition and dementia, and the number of cases with the condition is rising as the population ages. However, to date, no validated patient reported outcome measure (PRO) exists specifically in MCI. We report on a study to develop a PRO for use in MCI. **METHODS:** Semi-structured in-depth interviews were carried out with people with MCI in order to determine the questionnaire items. These interviews were audio-recorded, transcribed and content analysed. The draft questionnaire was refined following feedback from a focus group of patients with a diagnosis of MCI. Questionnaires were posted to subjects recruited from memory clinics and research databases, the completed questionnaires were analysed using factor analytic techniques to produce the final measure; construct validity was assessed by correlation with a generic patient reported outcome measure, the SF-12. **RESULTS:** Interviews were carried out with 23 people with MCI. 280 questionnaires were sent to subjects, with a response rate of 56% i.e.146 were included in the analysis. Factor analysis produced a 13 item measure tapping two domains of patient reported quality of life ('Emotional Effects' and 'Practical Concerns'). Internal consistency reliability was high for both domains (alpha was 0.91 and 0.85 respectively). Both dimensions were found to be highly and significantly correlated with the Mental Component Summary score of the SF-12. **CONCLUSIONS:** The Mild Cognitive Impairment Questionnaire (MCQ) is a short 13 item measure developed specifically to measure patient reported outcomes in people with MCI. It was created on the basis of patient report, and has been shown to have good psychometric properties. It is likely to prove valuable in the evaluation of treatment regimes in this important and growing patient group.

PMH52

SCORING THE CENTER FOR EPIDEMIOLOGIC STUDIES – DEPRESSION SCALE: WHICH ITEMS GO WHERE?

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OBJECTIVES: To guide researchers on the best way to score the Center for Epidemiologic Studies – Depression scale (CES-D) by comparing competing models in the literature. **METHODS:** Radloff (19777), the original CES-D author, first provided scoring for four uncorrelated factors of depression: negative affect (NA), positive affect (PA), interpersonal (I), and somatic (S). Sheehan et al. (1995) validated four correlated factors in the CES-D. However, Radloff and Sheehan results may have differed because Radloff ascribed items of *failure* and *fearful*to NA whereas Sheehan assigned a value of I. Following Sheehan's scoring, Cole et al. (2004) presumed a hierarchical factor of depressed mood that included all four previously identified factors and posited a 10-item short-form of the CES-D. These four models were compared using structural equation modeling for parametric models with Bollen-Stine bootstraps to control for multivariate nonnormality in 225 community-residing subjects, structural validity of the models were compared. **RESULTS:** Fit statistics for the four models were: Radloff comparative fit index (CFI) = .790 & root mean square error of approximation (RMEA) = .011; Sheehan CFI = .926 & RMSEA = .053, Cole hierarchical CFI = .927 & RMSEA = .052; Cole 10-item CFI = .979 & RMSEA = .041 **CONCLUSIONS:** The uncorrelated Radloff model was the poorest fit the day. Both Sheehan and Cole 20-item models were decently fit to the data and nearly identical to each other in fit. Finally, the 10-item Cole short-form of the CES-D was the best fit model to the data. Given the brevity of this form and strong fit with the theoretical structure postulated by Radloff, researchers may want to consider this form of the CES-D for research on depressed mood.

PMH53

PREVALENCE AND RISK FACTORS OF DEPRESSION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE IN INDIA

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OBJECTIVES: Although depression is a significant co-morbid condition in chronic illness, little is known about the prevalence or risk factors for depressive symp-